

Food and Drug Administration, HHS

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matter and includes action on a new drug application, new animal drug application, or biological license.

Participant means any person participating in any proceeding, including each party and any other interested person.

Party means the center of the Food and Drug Administration responsible for a matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a hearing under part 12 or part 16 or who has waived the right to a hearing to obtain the establishment of a Public Board of Inquiry under part 13 and as a result of whose action a hearing or a Public Board of Inquiry has been established.

Person includes an individual, partnership, corporation, association, or other legal entity.

Petition means a petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration.

Presiding officer means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.

Proceeding and *administrative proceeding* means any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

Public advisory committee or *advisory committee* means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup of an advisory committee, that is not composed wholly of full-time employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

Public Board of Inquiry or *Board* means an administrative law tribunal constituted under part 13.

Public hearing before a public advisory committee means a hearing conducted under part 14.

Public hearing before a Public Board of Inquiry means a hearing conducted under part 13.

Public hearing before the Commissioner means a hearing conducted under part 15.

Regulations means an agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with §10.90(a), each agency regulation will be published in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

Regulatory hearing before the Food and Drug Administration means a hearing conducted under part 16.

Secretary means the Secretary of Health and Human Services.

The laws administered by the Commissioner or the laws administered by the Food and Drug Administration means all the laws that the Commissioner is authorized to administer under §5.10.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a center, the reference includes all persons to whom that person has delegated the specific function involved.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 8994, Mar. 6, 1985; 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994]

§10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative practices and procedures in readily understandable terms.

§10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the

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request of a participant, waive, suspend, or modify any provision in parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

Subpart B—General Administrative Procedures

§ 10.20 Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure.

(a) A submission to the Dockets Management Branch of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant FEDERAL REGISTER notice or in another section of this chapter. The Dockets Management Branch is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of § 10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is:

- (i) A reported Federal court case;
- (ii) A Federal law or regulation;
- (iii) An FDA document that is routinely publicly available; or
- (iv) A recognized medical or scientific textbook that is readily available to the agency.

(2) If a part of the material submitted is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. A translation of literature or other material in a foreign language is to be ac-

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companied by copies of the original publication.

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under § 20.63 (a) and (b), the names and other information that would identify patients or research subjects are to be deleted from any record before it is submitted to the Dockets Management Branch in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter is to be deleted from a record before it is submitted to the Dockets Management Branch.

(6) The failure to comply with the requirements of this part or with § 12.80 or § 13.20 will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply. If a submission fails to meet any requirement of this section and the deficiency becomes known to the Dockets Management Branch, the Dockets Management Branch shall not file the submission but return it with a copy of the applicable regulations indicating those provisions not complied with. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Dockets Management Branch does not make decisions regarding the confidentiality of submitted documents. Persons wishing to voluntarily submit information considered confidential shall follow the pre-submission review requirements of § 20.44.

(d) The filing of a submission means only that the Dockets Management Branch has identified no technical deficiencies in the submission. The filing of a petition does not mean or imply that it meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Dockets Management Branch will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the date